

REMARKS

Claims 1-58 are currently pending in this application. Claims 1-11, 13-15, 17-20 and 32-58 are rejected and claims 12, 16 and 21-31 are objected to.

Applicants acknowledge and appreciate the Examiner's favorable reconsideration of claims 12, 16 and 21-31 and recognition of the substantive patentability of those claims.

Claim 1 has been amended to more particularly define what the Applicants regard as their invention by claiming the composition as a "self-emulsifying drug delivery system". Support for this amendment can be found on page 2, lines 19-21.

Claim 2 has been amended to more particularly define what the Applicants regard as their invention by claiming the composition as "optically isotropic and thermodynamically stable". Support for this amendment can be found on page 15, line 7 and line 13.

Claim 6 has been cancelled as being duplicative of newly amended claim 2.

No new matter has been added by way of these amendments.

I. Rejections under 35 U.S.C. §112 – New Matter

Claims 55- 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the subject matter was not sufficiently described in the specification.

Applicants respectfully submit that the specification reasonably conveys to one skilled in the art that the inventors were in possession of the invention. The levorotatory form of modafinil is specifically described in the specification on page 1, lines 30-34, and is further described in U.S. Pat. No. 4,927,855, which is incorporated into the specification by

reference. The definition of a "modafinil compound" refers to modafinil and its *individual isomers* (emphasis added) on page 4, line 30. As the levorotatory form of modafinil is an individual isomer of modafinil (which is itself a racemic mixture), Applicants respectfully submit that the subject matter of claims 55-57 are adequately supported by the specification.

In view of the above amendments and remarks, reconsideration and withdrawal of the rejections under § 112 is respectfully requested.

II. Rejections under 35 U.S.C. §102

Grebow:

Claims 1-4, 6, 32, 33, 36, 37, 39, 41-44, 47, 48, 51, 52, 54, and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Grebow, et al. (US 5,618,845) for reasons set forth in the Office Action.

Applicants respectfully submit that the amendments to claim 1 more fully describe the Applicants invention and that all elements of the current invention are not disclosed by the reference, so the rejection is unsupported by the art. The Grebow reference fails to teach a self-emulsifying drug delivery system.

As for newly amended claim 2, Applicants respectfully submit that contrary to the Examiner's assertion that all elements of the current invention are disclosed by the reference, optically isotropic and thermodynamically stable aqueous compositions are not, so the rejection is unsupported by the art.

Nguyen:

Claims 1-4, 6, 7, 11, 14, 15, 32, 33, 36, 37, 39, 47, 51 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Nguyen et al. (US5,843,347) for reasons set forth in the Office Action.

Applicants respectfully submit that the reference does not teach all the elements of the

claimed invention. Claim 1 of the instant invention involves a composition that is a self-emulsifying drug delivery system. Nguyen does not teach that the compositions disclosed therein are self-emulsifying drug delivery systems. One skilled in the art who practices the teachings of Nguyen will not create the self-emulsifying drug delivery systems of the instant invention. Claim 2 of the instant invention involves optically isotropic and thermodynamically stable aqueous compositions. Nguyen does not teach that the compositions disclosed therein are optically isotropic and thermodynamically stable. One skilled in the art who practices the teachings of Nguyen will not create the optically isotropic and thermodynamically stable compositions of the instant invention.

In view of the above amendments and remarks, reconsideration and withdrawal of the rejections under §102, and allowance of the claims is respectfully requested.

III. Rejections under 35 U.S.C. §103

Grebow:

Claims 17, 18, 34, 35, 38, 45, 46, 49, 50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845) for reasons set forth in the Office Action.

Applicants respectfully submit that the reference does not teach the claimed invention. Claim 1 of the instant application involves a composition that is a self-emulsifying drug delivery system. Claim 2 of the instant application involves optically isotropic and thermodynamically stable aqueous compositions. Grebow teaches conventional emulsions comprising a modafinil compound. Such emulsions, as understood by those skilled in the art, are fundamentally different from the self-emulsifying drug delivery systems and the optically isotropic and thermodynamically stable aqueous compositions disclosed in the instant application. Hence Grebow fails to teach the disclosure of the instant application, and as such

the instant claims are non-obvious.

Nguyen in view of Lafon:

Claims 8-10, 13, 17-20, 34, 35, 38 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Lafon (US 5,180,745) for reasons set forth in the Office Action.

Applicants respectfully submit that the references, alone or in combination, do not teach the claimed invention. Claim 1 of the instant application involves a composition that is a self-emulsifying drug delivery system. Claim 2 of the instant application involves optically isotropic and thermodynamically stable aqueous compositions. Nguyen teaches the preparation of aqueous "pasty mixtures" which are to be extruded and lyophilized to form solid macroparticles (see Abstract). There is no teaching of the possible formation of non-crystalline particles from these formulations. Furthermore the formulations disclosed in Nguyen are fundamentally different from the self-emulsifying drug delivery systems and the optically isotropic and thermodynamically stable aqueous compositions disclosed in the instant application.

Applicants respectfully submit that Lafon does not cure the deficiencies of Nguyen. Lafon teaches subcutaneous injection of 0.4% suspension of modafinil. Such suspensions do not contain non-crystalline particles of modafinil and such suspensions are fundamentally different from the self-emulsifying drug delivery systems and the optically isotropic and thermodynamically stable aqueous compositions disclosed in the instant application.

Hence, the claims of the current application have not been taught nor suggested by the prior art, alone or in combination, and as such are non-obvious.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845) in view of Lafon (US 4,927,855) for reasons set forth in the Office Action.

Applicants respectfully submit that the references, alone or in combination, do not teach the claimed invention. As discussed above, Grebow fails to teach the claimed invention. Applicants respectfully submit that Lafon does not cure the deficiencies of Nguyen. Lafon teaches intraperitoneal injection of modafinil in an aqueous solution of gum arabic and administration of tablets or gelatin capsules. These formulations are fundamentally different from the self-emulsifying drug delivery systems and the optically isotropic and thermodynamically stable aqueous compositions disclosed in the instant application.

Hence, the claims of the current application have not been taught nor suggested by the prior art, alone or in combination, and as such are non-obvious.

In view of the above amendments and remarks, reconsideration and withdrawal of the rejections under §103 is respectfully requested.

IV. Double Patenting Rejection

Claims 1, 3-5, 14, 15, 32-35 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 8, 10-13, 26-29, 31 and 32 of US Patent No. 6,489,363.

Although Applicants do not agree that the pending claims are obvious in view of the '363 patent, the rejection can likely be overcome, for example, through the filing of a terminal disclaimer upon an indication of allowable subject matter rejection.

V. Objections

Claims 12, 16 and 21-31 are objected to as being dependent upon a rejected base claim.

Although Applicants submit that the base claims are patentable, the rejection can

likely be overcome, for example, by converting the objected-to claims to independent claims should they be the only allowable subject matter. Accordingly, Applicants will address this rejection upon further indication of allowable subject matter in the present application.

Conclusion

In view of the above, it is requested that the amendments and remarks be entered. It is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested. Applicants invite the Examiner to contact the undersigned at (610) 738-6465 to clarify any unresolved issues raised by this response.

Respectfully submitted,


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